REMARKS

Claim status

Claims 1-6, 8, 14-18, and 26-33 were pending in the case at the time of the current Office Action. Claim 33 is cancelled herein. New claim 34 is added herein. No new matter has been added. Claims 1-6, 8, 14-18, and 26-32, and 34 are currently pending in the application. There are a total of 20 claims currently pending in the application.

Section 102 rejections

In the current Office action, claims 1-3 and 33 are rejected under 35 U.S.C. 102(b) as being anticipated by Housworth et al. (USPN 5,443,485).

Applicants respectfully traverse the foregoing rejection in view of the above pending claims and for reasons set forth hereafter.

Independent claim 1 recites a stimulation arrangement, comprising:

a stimulation unit to deliver electrical stimulation pulses for stimulating body tissue; and

an evaluation unit to receive at least one electrical signal in conjunction with the delivery of a stimulation pulse and to evaluate said received electrical signal for checking both stimulation success and lack of stimulation success, and wherein the evaluation unit is capable of detecting first signal features in the received electrical signal that characterize a case of lack of stimulation success, and delivering a corresponding first output signal, and wherein the evaluation unit is capable of detecting second signal features in the received electrical signal that characterize a case of stimulation success, and delivering a corresponding second output signal.

It is respectfully submitted that Housworth et al. (USPN 5,443,485), hereinafter Housworth, does not teach or suggest the claimed invention. In particular, Housworth does teach or suggest evaluating a received electrical signal for checking both stimulation success and lack of stimulation success, and wherein the evaluation unit is capable of detecting first signal features in the received electrical signal that characterize a case of lack of stimulation success,

and delivering a corresponding first output signal, and wherein the evaluation unit is capable of detecting second signal features in the received electrical signal that characterize a case of stimulation success, and delivering a corresponding second output signal.

In the claimed invention of claim 1, if the stimulation pulse is not effective, only a signal (e.g., a polarization artefact) having characteristic features that are characteristic of a lack of stimulation success are detected. If the stimulation pulse is effective, an evoked response is detected that also comprises characteristic features that are different from the features of the polarization artefact. In the claimed invention of claim 1, two distinct type of signal features are looked for:

1. those signal features indicating lack of stimulation success (test 1)
   (e.g., features of the polarization artefact)
2. those signal features indicating stimulation success (test 2)

The claimed invention of claim 1 generates a capture signal based on the detection of first certain signal features, and generates a non-capture signal based on the detection of second certain signal features. Fig. 2 of the present application shows a graphical example of a signal having features characterizing a lack of stimulation success. Figs. 3 and 4 of the present application show graphical examples of signals having features characterizing stimulation success.

Housworth describes that the sensed signal is only analyzed for features being characteristic for an evoked response (capture or stimulation success) or an intrinsic excitation, but not for any feature being characteristic of non-capture or lack of stimulation success (e.g., the polarization artefact alone). This becomes clear from the complete description since, according to Housworth, the sensed signal is filtered to remove any polarization voltage, thus eliminating the polarization artefact (see column 3, lines 11 to 16). In order to enable reliable capture detection, according to Housworth, signal features due to polarization are eliminated and thus signal features representing the myocardial reaction to an effective stimulation pulse are pronounced.

Therefore, the device of Housworth is not capable of detecting any characteristic feature of a polarization artefact, as does the claimed invention to determine a lack of stimulation success. Housworth is directed to detecting the difference between the capture and the non-capture morphologies of the signal detected by the pacing lead (see column 2, lines 62-65).

Housworth does not teach or suggest performing a positive identification of both a polarization artefact (lack of stimulation success) and an evoked response (stimulation success). In the claimed invention, a sensed signal is compared both to features characterizing a polarization artefact (lack of stimulation success) and to features characterizing an evoked response (capture or stimulation success).

The claimed invention is directed to detecting positive features of the capture morphologies of the signal detected by the pacing lead, and positive features of the non-capture morphologies of the signal detected by the pacing lead. Housworth concentrates on detecting those features that render a capture morphology of the signal detected by the pacing lead different from a non-capture morphology of the signal detected by the pacing lead.

For example, as described in column 3 of Housworth, the signal is first bandpass filtered to eliminate high-frequency noise and to remove much of the effect of the lead polarization voltage. The signal is then highpass filtered to remove any remaining polarization voltage and to accentuate the evoked response signal. The resultant filtered signal is integrated over a short time window starting at a selected delay following delivery of the pacing pulse. The output of the integrator is passed to a comparator having a reference voltage. If the value of the integral goes above the reference voltage within the integration window, the comparator goes to a logic high level, indicating that capture has occurred. This method of Housworth clearly shows that Housworth is looking at only one feature (the integrated filtered signal) that characterizes a case of stimulation success. Housworth is not looking at any other feature that characterizes a case of lack of stimulation success as does the claimed invention of claim 1. In fact, Housworth in effect teaches away from the claimed invention by filtering out the very signal (the polarization artefact) that may be used to extract features that characterize a lack of stimulation success as in the claimed invention. Housworth does not teach or suggest detecting any other signal features that characterize a lack of stimulation success.

Further, it should be emphasized that Housworth is directed to discriminate an evoked (stimulation) response from an intrinsic natural contraction of the heart. For example, as described in column 3 of Housworth, intrinsic contractions that occur near the time of delivery of a non-capturing stimulating pulse may generate relatively large signals that fall within the integration window. Such intrinsic contractions result in the integrator stage having very large

output values that could cause the voltage reference to be exceeded in the comparator stage, leading to a false detection of capture. Therefore, Housworth may use two comparators with different reference voltages. One comparator is set with a high reference level that will only be exceeded in the case of an intrinsic contraction. The other comparator is set with a lower reference level selected to detect capture signals. If both comparators indicate that their respective reference levels have been exceeded by the end of the integration window, an intrinsic contraction has occurred. If only the comparator with the lower reference level indicates that its reference level has been exceeded, a capture has occurred. If both comparators indicate that their respective reference levels have not been exceeded, a determination is made that capture has not occurred. Again, only one feature (the integrated filtered signal) is being used to determine capture or intrinsic contraction. If capture or intrinsic contraction is not determined from this feature, then non-capture is assumed.

Therefore, unlike the claimed invention of claim 1, Housworth does not use first signal features (for determining a lack of capture stimulation success) and second signal features (for determining stimulation success) based on the received signal. In fact, Housworth throws away the very information (the polarization artefact) that could be used to positively determine a lack of stimulation success.

In summary, Housworth is effectively generating one feature (an integrated filtered value) and using that to determine stimulation success and/or intrinsic contraction.

Therefore, in view of at least the foregoing, it is respectfully submitted that claim 1 is neither anticipated nor rendered obvious, and it is respectfully submitted that claim 1 now defines allowable subject matter. Also, since claims 2-3 and 33 depend either directly or indirectly from claim 1, it is respectfully submitted that claims 2-3 and 33 define allowable subject matter as well. Applicants respectfully request that the rejection of claims 1-3 and 33 under 35 U.S.C. 102(b) be removed.

Allowable Subject Matter

Applicants thankfully acknowledge the Examiners assertion that claims 4-6, 8, 14-18, and 26-32 would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims, even though Applicants believe and have argued herein that independent claim 1 is allowable on its own.

New independent claim 34 has been added herein which incorporates claim 14 into claim 1. Therefore, according to the Examiner, new independent claim 34 should be allowable.

Accordingly, the applicant respectfully requests reconsideration of the rejections based on the arguments made above. After such reconsideration, it is urged that allowance of all claims will be in order.

Respectfully submitted,

David J. Muzilla
Registration No. 50,914

Hahn Loeser & Parks LLP
One GOJO Plaza
Suite 300
Akron, OH 44311-1076
(330) 864-5550
Fax 330-864-7986
dmuzilla@hahnlaw.com

CUSTOMER No. 021324